U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

RAJESH NAHAR and THIRUKUMARAN VELAYUDHAN, Derivatively on Behalf of Nominal Defendant, CTI BIOPHARMA CORP., Plaintiffs, vs. JAMES A. BIANCO, LOUIS A. BIANCO, BRUCE J. SEELEY, JACK W. SINGER, PHILLIP M. NUDELMAN, JOHN H. BAUER, KAREN IGNAGNI, RICHARD L. LOVE, MARY O. MUNDINGER, FREDERICK W. TELLING and REED V. TUCKSON, Defendants, and CTI BIOPHARMA CORP., Nominal Defendant.	NO. **VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT** **Jury Trial Demand**

INTRODUCTION

1. Plaintiffs Rajesh Nahar and Thirukumaran Velayudhan ("Plaintiffs"), by and through their undersigned attorneys, submit this Verified Shareholder Derivative Complaint (the "Complaint") against defendants named herein. Plaintiffs allege the following based upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among

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other things, counsel's investigation, which includes, without limitation: (a) a review and analysis of regulatory filings filed by CTI Biopharma Corp. ("CTI" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) a review and analysis of press releases and media reports issued and disseminated by CTI; and (c) a review of other publicly available information concerning CTI. Plaintiffs are current shareholders of the Company and were shareholders at the time of the transactions complained of herein. This derivative action is not a collusive one to confer jurisdiction on a court of this state which it would not otherwise have.

SUMMARY OF THE ACTION

2. This is a shareholder's derivative action brought for the benefit of Nominal Defendant CTI. CTI is a biopharmaceutical company which provides medical research services and develops clinical treatment and drugs for various cancers. One of the Company's most advanced pipeline products was pacritinib, a treatment for myelofibrosis. CTI is headquartered in Seattle, Washington. The Company's clinical trials of pacritinib are referred to as the PERSIST program.

3. This derivative action is brought against certain members of the Company's Board of Directors (the "Board") and certain of its executive officers (collectively, the "Individual Defendants") seeking to remedy the Defendants' violations of state law and breaches of fiduciary duty during the period beginning March 3, 2014 through the present (the "Relevant Period").

4. Defendants' breaches of fiduciary duty began on March 3, 2014, when they caused the Company to file a Form 8-K with the SEC accompanied by a press release touting pacritinib that was materially false and misleading. The next day, on March 4, 2016, Defendants caused the Company to file its Annual Report on Form 10-K that was materially false and misleading for a variety of reasons as described below in ¶ 91, including its positive representations about pacritinib and the Company's internal controls.

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5. These materially false and misleading statements continued unabated until February 8, 2016, when the Company issued a press release prior to the opening of the market announcing that a partial clinical hold had been placed on the pacritinib Phase 3 clinical trials by the Food and Drug Administration ("FDA"). *See,* ¶¶ 70, 72-79, 81-86 and 88-89. As a result of this news, CTI's shares declined $0.68 per share, or over 60% to close at $0.44 on February 8, 2016.

6. On February 10, 2016, at exactly 12:00 a.m., the Company issued a press release announcing that the Company had been informed by the FDA that a full clinical hold had been placed on the pacritinib Phase 3 clinical trials. The market cratered again, as shares fell over 40% in intra-day trading to close at $0.30. Further, on September 24, 2015, in the midst of peppering the marketplace with materially false and misleading positive statements about pacritinib, the Defendants filed a Registration Statement/Prospectus Supplement, pricing an offering of 10,000,000 shares at a price of $1.57 per share, which was equally materially false and misleading.

7. As a result of the revelations on February 8 and 10, 2016, the Company is now subjected to two class action securities lawsuits alleging the following violations of the federal securities laws on behalf of purchasers of CTI stock: (a) Sections 11 and 15 of the Securities Act of 1933 for shares purchased pursuant and/or traceable to the Company's Registration Statement/Prospectus Supplement ("Registration Statement/Prospectus Supplement") issued in connection with the Company's public offering on or about September 24, 2015 (the "Offering"); and/or (b) Sections 10(b), 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by the SEC for shares purchased on the open market between March 3, 2014 and February 9, 2016, inclusive (the "Class Period"). The cases are currently pending in the United States District Court for the Southern District of New York and the

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United States District Court for the Western District of Washington, respectively (hereinafter the "Securities Class Actions").[1]

8. Further, the Company's stock has remained below $1.00 for over 30 continuous business days prompting The NASDAQ Stock Market to issue a Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard on March 22, 2016. According to NASDAQ Listing Rule 5810(c)(3)(A), the Company has until September 19, 2016, to regain compliance with the $1.00 per share minimum requirement. Otherwise, the Company's stock will be delisted. The Company's stock is currently trading in the $0.40 - $0.47 per share range well below the required $1.00 per share minimum needed for compliance.

9. Most importantly, the Board was put on notice that "the Independent Data Monitoring Committee ("IDMC"), in place at the time for the PERSIST program recommended patients on the best available therapy, or BAT, arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks ..." The Board rejected the recommendation and "determined that no modifications to the ongoing trials were required." This was disclosed for the first time in the Registration Statement/Prospectus Supplement filed with the SEC on September 24, 2015.

10. According to the FDA, a clinical trial data monitoring committee or, DMC, is a "group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing trials. The DMC advise the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial." Additionally, the DMC also has other responsibilities including but not limited to, making recommendations to the sponsor of the clinical trial (which, in this instance was the IDMC's recommendation to CTI for patients not to crossover as described above in ¶ 8).

[1] The cases are docketed at: *Ahrens et al. v. CTI Biopharma Corp. et al.,* Case No: 1:16-cv-01044; *McGlothin v. CTI Biopharma Corp.*, et al., Case No. 2:16-cv-00216.

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11. The news continued to get worse after the February 8 and February 10 revelations. On May 10, 2016, the Company filed its Form 10-Q for the first quarter ended March 31, 2016, revealing for the first time that the Company had received a subpoena back in January 2016, even before the revelations concerning the partial and full clinical holds had been disclosed in early February 2016. The Form 10-Q stated:

> We are also in the process of providing documents in response to a subpoena received from the SEC in January 2016. The SEC's subpoena requests, among other things; internal and external communications related to pacritinib Phase 3 trials, including communications with the independent data monitoring committee, or IDMC, for pacritinib's Phase 3 trials, our steering committee, our board of directors, our audit committee, representatives of Baxter and Baxalta, and the Food and Drug Administration, and other documents related to pacritinib. We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib.

The Defendants waited approximately four months before publicly disclosing that the SEC was conducting an investigation into "possible violations of the anti-fraud provisions of the federal securities laws" related to CTI's disclosures concerning clinical test results involving pacritinib. With the Board and Audit Committee targets of the subpoena, the entire Board is at risk of substantial liability.

12. The Individual Defendants' violations arise from a course of misconduct whereby they breached their duties of loyalty, care and good faith by: (i) issuing and/or permitting to be issued false and misleading statements about the Company's business, operations and prospects and/or failing to disclose (a) that pacritinib was attributed to a potential cause in the death and injuries of several patients; (b) that the Company's clinical trials showed the dangers of pacritinib usage; and (c) that the Company's new drug application for pacritinib would likely be withdrawn; (ii) consciously disregarding the recommendation by the IDMC in place during the PERSIST trials advising against allowing patients to crossover;

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(iii) failing to exercise their oversight duties by not monitoring safety while the pacritinib clinical trials were taking place especially after being put on notice that the IDMC advised against allowing patients to crossover; (iv) failing to make modifications to its ongoing pacritinib clinical trials when put on notice that the design of the PERSIST clinical trials could result in in non-statistically significant safety concerns; and (v) failing to maintain and/or implement a system of effective internal controls and procedures with respect to the development and commercialization of pacritinib.

13. The Company has suffered substantial damages as a result of the Individual Defendants' breaches of fiduciary duty. CTI has expended and will continue to expend significant sums of money. Additional expenditures and damages that the Company has incurred as a result of the Individual Defendants' breaches of their fiduciary duty include:

a. costs incurred from investigating, defending and paying any settlement or judgment in the Securities Class Actions for violations of federal securities laws;

b. costs incurred from conducting additional studies and/or for pacritinib in patients with myelofibrosis;

c. costs incurred from complying with the FDA's recommendations to the Company in connection with the FDA's decision to place a full clinical hold on the Company's IND for pacritinib, including, but not limited to, conducting dose exploration studies for pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols;

d. costs incurred from preparing and resubmitting the NDA for pacritinib;

e. costs incurred from the loss of CTI's customers' confidence in the

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Company's services, and

f. costs incurred in connection with the SEC investigation and possible fines and/or penalties based on the SEC's findings

14. Demand is futile because a majority of the current Board is neither independent nor disinterested. The Current Board is made up of seven members, six of whom are named defendants in the Action. Two members of the current Board are also officers of the Company and, as such, are considered insiders who lack independence. All six of the current Board members who are defendants in the Action are also defendants in the Securities Class Actions and therefore lack independence because they each face a substantial likelihood of liability in the Securities Class Actions and have taken the position in SEC filings that the allegations of the Securities Class Actions "are without merit." Thus, these six current Board members are already predisposed to not taking any action whatsoever in connection with any potential litigation demand made upon them and instead "intend to vigorously defend ourselves against all claims asserted therein." Demand is therefore, futile.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity among the parties and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

16. This Court has jurisdiction over each Defendant named herein because each Defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contact with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

17. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) because one or more of the defendants either resides in or maintains executive offices in this District, a substantial portion of the transactions and wrongs complained of herein, including defendants'

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primary participation in the wrongful acts detailed herein and aiding in violation of fiduciary duties owed to CTI occurred in this District and defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that have an effect in this District.

PARTIES

18. Plaintiff Rajesh Nahar is currently and has continuously been a stockholder of CTI since before the beginning of the Relevant Period.

19. Plaintiff Thirukumaran Velayudhan is currently and has continuously been a stockholder of CTI since before the beginning of the Relevant Period.

20. Nominal Defendant CTI is incorporated under the laws of the State of Washington and maintains its headquarters in Seattle, Washington. According to the Company's SEC filings, CTI describes itself as a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and health care providers. CTI's shares are listed and traded on the NASDAQ Exchange under the ticker "CTIC." As of February 10, 2016, the Company had 280,555,401 shares of the Company's common stock outstanding.

21. Defendant James A. Bianco ("J. Bianco") is the principal founder of CTI and has served as the Company's Chief Executive Officer ("CEO") and a director since September 1991. He has also served as President of CTI since July 2012, as well as from February 1992 through July 2008. J. Bianco also is a member of the Company's Scientific Advisory Board. J. Bianco is the brother of Defendant Louis A. Bianco. According to the Company's proxy statement filed on Schedule 14A with the SEC on March 17, 2016 (the "2016 Proxy"), the Company stated: "Dr. Bianco's experience as a founder and executive of the Company and his knowledge of biopharmaceuticals were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." J. Bianco signed or authorized

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the signing of the Registration Statement/Prospectus Supplement as CEO. J. Bianco is a defendant in the Securities Class Actions. Upon information and belief, J. Bianco is a citizen of Washington.

22. Defendant Louis A. Bianco ("L. Bianco") is a founder of CTI and has served as the Company's Executive Vice President, Finance and Administration since February 1992. He previously served as a director of CTI from September 1991 to April 1992 and from April 1993 to April 1995. Defendant L. Bianco is the brother of Defendant J Bianco. L. Bianco signed or authorized the signing of the Registration Statement/Prospectus Supplement. L. Bianco is a defendant in the Securities Class Action. Upon information and belief, L. Bianco is a citizen of Rhode Island.

23. Defendant Bruce J. Seeley ("Seeley") has served as Executive Vice President, Chief Commercial Officer of the Company since July 2015. Seeley leads CTI's commercial organization worldwide, including sales, marketing, commercial operations, medical affairs and supply chain. Seeley is a defendant in the Securities Class Actions. Upon information and belief, Seeley is a citizen of Washington.

24. Defendant Jack W. Singer ("Singer") is a founder of CTI and currently serves as the Company's Executive Vice President, Chief Scientific Officer, Interim Chief Medical Officer and Global Head of Translational Medicine. Singer has served as a director of the Company since September 1991. Singer is also a member of the Company's Scientific Advisory Board. From July 1995 to January 2004, Singer served as the Company's Executive Vice President, Research Program Chairman, and from April 1992 to July 1995, he served as the Company's Executive Vice President, Research and Development. According to the 2016 Proxy, the Company stated: "Dr. Singer's experience as a founder and executive of the Company and experience as a medical doctor and in the pharmaceutical and biotechnology industries were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." Singer signed or authorized the signing of the

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Registration Statement/Prospectus Supplement. Singer is a defendant in the Securities Class Actions. Upon information and belief, Singer is a citizen of Washington.

25. Defendant Phillip M. Nudelman ("Nudelman") has served as a director of the Company since March 1994 and as Chairman of the Board since October 2005. Nudelman is also the Chair of the Nominating and Governance Committee and is a member of the Audit Committee and the Compensation Committee. According to the 2016 Proxy, the Company stated: "Dr. Nudelman's business and management experience and his experience investing in biotechnology companies were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." Nudelman signed or authorized the signing of the Registration Statement/Prospectus Supplement. Nudelman is a defendant in the Securities Class Actions. Upon information and belief, Nudelman is a citizen of Washington.

26. Defendant John H. Bauer ("Bauer") previously served as a director of the Company from October 2005 until his resignation from the Board on October 20, 2015. Prior to his resignation, Bauer was the Chair of the Audit Committee. Bauer signed or authorized the signing of the Registration Statement/Prospectus Supplement. Bauer is a defendant in the Securities Class Actions. Upon information and belief, Bauer is a citizen of Washington.

27. Defendant Karen Ignagni ("Ignagni") previously served as a director of the Company from January 2014 until her resignation from the Board on November 5, 2015. Ignagni signed or authorized the signing of the Registration Statement/Prospectus Supplement. Ignagni is a defendant in the Securities Class Actions. Upon information and belief, Ignagni is a citizen of New York.

28. Defendant Richard L. Love ("Love") has served as a director of the Company since September 2007. Love is currently the Chair of the Audit Committee and is described by the Company as an "audit committee financial expert," as defined under the rules and regulations of the SEC and that he has accounting and related financial management expertise within the meaning of the NASDAQ Stock Market rules. He is also a member of the

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Compensation Committee and the Nominating and Governance Committee. According to the 2016 Proxy, the Company stated: "Mr. Love's many years of experience as an executive in the pharmaceutical biotechnology and medical research industries were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." Love signed or authorized the signing of the Registration Statement/Prospectus Supplement. Love is a defendant in the Securities Class Actions. Upon information and belief, Love is a citizen of Texas.

29. Defendant Mary O. Mundinger ("Mundinger") served as a director of the Company from April 1997 until April 29, 2016. Mundinger was a member of the Compensation Committee and the Nominating and Governance Committee. Mundinger signed or authorized the signing of the Registration Statement/Prospectus Supplement. Mundinger is a defendant in the Securities Class Action. Upon information and belief, Mundinger is a citizen of New York.

30. Defendant Frederick W. Telling ("Telling") has served as a director of the Company since December 2006. Telling is the Chair of the Compensation Committee, and is also a member of the Audit Committee. According to the 2016 Proxy, the Company stated "Dr. Telling's business and industry experience as well as experience as a director of public companies were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." Telling signed or authorized the signing of the Registration Statement/Prospectus Supplement. Telling is a defendant in the Securities Class Actions. Upon information and belief, Telling is a citizen of New York.

31. Defendant Reed V. Tuckson ("Tuckson") has served as a director of the Company since September 2011. Tuckson is a member of the Nominating and Governance Committee. According to the 2016 Proxy, the Company stated "Dr. Tuckson's experience as a healthcare executive and consultant across health and medical care sectors were the primary qualifications that have led the Board to conclude that he should serve as a director of the

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Company." Tuckson signed or authorized the signing of the Registration Statement/Prospectus Supplement. Tuckson is a defendant in the Securities Class Actions. Upon information and belief, Tuckson is a citizen of Georgia.

32. Defendants J. Bianco, Love, Nudelman, Singer, Telling and Tuckson are sometimes collectively referred to herein as the "Current Director Defendants."

33. Defendants J. Bianco, L. Bianco, Seeley, Singer, Nudelman, Bauer, Ignagni, Love, Mundinger, Telling and Tuckson are sometimes collectively referred to herein as the "Individual Defendants."

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

34. By reason of their positions as officers, directors and/or fiduciaries of CTI during the Relevant Period and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owed CTI and its shareholders fiduciary obligations of good faith, loyalty and candor, and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of CTI and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

35. Each director and officer of the Company owes to CTI and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company's affairs and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

36. The Individual Defendants, because of their positions of control and authority as directors and/or officers of CTI, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Due to their positions with CTI, each of

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the Individual Defendants had knowledge of material non-public information regarding the Company.

37. To discharge their duties, the Individual Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of CTI were required to, among other things:

a. exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

b. exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal, state and foreign laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority;

c. exercise good faith in supervising the preparation, filing and/or dissemination of financial statements, press releases, audits, reports or other information required by law, and in examining and evaluating any reports or examinations, audits, or other financial information concerning the financial condition of the Company;

d. refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

e. when put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

38. Moreover, CTI maintains a Code of Business Conduct and Ethics (the "Code"), which applies to the Company's officers, directors, employees, contract workers and agents of

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CTI, its subsidiaries, branches, divisions, and affiliates, whether operating inside or outside of the United States. The Code states that it "helps ensure compliance with legal and regulatory requirements and provides guidance on standards of business conduct, which apply to [the Company's] relationships with customers, vendors, suppliers, government entities and to each other."

39. Additionally, CTI maintains a Code of Ethics for Senior Executives and Financial Officers (the "Code of Ethics"), which applies to CTI's chief executive officer, chief financial officer, chief operating officer, comptroller, director of finance and accounting, and principal accounting officer. The purpose of the Code of Ethics is to "promote the honest and ethical conduct of the Senior Officers of CTI, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; full, fair, accurate, timely and understandable disclosure in periodic reports filed by CTI and compliance with all applicable rules and regulations applicable to CTI and its officers."

40. The Board has also adopted Amended and Restated Corporate Governance Guidelines ("Corporate Governance Guidelines"), which includes requirements for director qualifications, director responsibilities and outlines the Board's leadership structure.

41. The Company also has an Audit Committee, Compensation Committee, and Nominating and Governance Committee, all of which have their own charters setting forth requirements for director qualifications, director responsibilities and director authority.

42. According to the 2016 Proxy, the Company also has a Scientific Advisory Board which "assists management with respect to the strategic development of the Company's oncology portfolio and clinical programs, its business development relating to in-licensing and out-licensing opportunities and research and development activities in general, regulatory matters and the Company's use of translational and personalized approaches to therapeutic targets. The Scientific Advisory Board also assists the Board in its oversight of these activities."

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43. Finally, the CTI Board was responsible for risk oversight:

> **Risk Oversight**
>
> Companies face a variety of risks, including credit risk, liquidity risk and operational risk. The Board believes an effective risk management system will (i) timely identify the material risks that we face, (ii) communicate necessary information with respect to material risks to senior executives and, as appropriate, to the Board or relevant committee of the Board, (iii) implement appropriate and responsive risk management strategies consistent with our risk profile and (iv) integrate risk management into our decision-making.
>
> The Board takes the lead in overseeing risk management, and the Audit Committee makes periodic reports to the Board regarding briefings provided by management and advisers, as well as the Audit Committee's own analysis and conclusions regarding the adequacy of our risk management processes. Material risks are identified and prioritized by management, and each prioritized risk is referred to a committee of the Board or the full Board for oversight. For example, management refers strategic risks to the full Board, while financial risks are referred to the Audit Committee. The Board regularly reviews information regarding our credit, liquidity and operations, as well as the risks associated with each, and annually reviews our risk management program as a whole. Also the Compensation Committee reviews our compensation programs to help ensure that they do not encourage excessive risk-taking. Please see "Compensation Discussion and Analysis – Risk Considerations" for more information.
>
> In addition to the formal compliance program, the Board encourages management to promote a corporate culture that incorporates risk management into our corporate strategy and day-to-day business operations. The Board also continually works, with the input of our executive officers, to assess and analyze the most likely areas of future risks for us.
>
> Our Board believes that the processes it has established for overseeing risk would be effective under a variety of leadership frameworks and therefore do not materially affect its choice of leadership structure as described under "Leadership Structure" above.

44. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed to the Company and to its shareholders the fiduciary duty of loyalty, good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct

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of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officers of CTI, the absence of good faith on their part and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

45. The Individual Defendants breached their duties of loyalty, care and good faith by: (i) issuing and/or permitting to be issued false and misleading statements about the Company's business, operations and prospects and/or failing to disclose (a) that pacritinib was attributed to a potential cause in the death and injuries of several patients; (b) that the Company's clinical trials showed the dangers of pacritinib usage; and (c) that the Company's new drug application for pacritinib would likely be withdrawn; (ii) consciously disregarding the recommendation by the IDMC in place during the PERSIST trials advising against allowing patients to crossover; (iii) failing to exercise their oversight duties by not monitoring safety while the pacritinib clinical trials were taking place especially after being put on notice that the IDMC advised against allowing patients to crossover; (iv) failing to make modifications to its ongoing pacritinib clinical trials when put on notice that the design of the PERSIST clinical trials could result in in non-statistically significant safety concerns; and (v) failing to maintain and/or implement a system of effective internal controls and procedures with respect to the development and commercialization of pacritinib.

SUBSTANTIVE ALLEGATIONS

Background

46. CTI is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and health care providers. The Company was incorporated in 1991. In May 2014, the Company changed its name from "Cell Therapeutics,

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Inc." to "CTI BioPharma Corp." The Company completed its initial public offering in 1997 and its shares are listed on The NASDAQ Capital Market in the United States.

47. In its annual report filed on Form 10-K with the SEC on February 17, 2016 for the fiscal year ended December 31, 2015 (the "2015 10-K"), the Company states that its "goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners." The Company further states that it is "concentrating [its] efforts on treatments that target blood-related cancers where there is an unmet need." These efforts include "evaluating pacritinib for the treatment of adult patients with myelofibrosis."

The Development, Commercialization and Licensing Agreement

48. On November 14, 2013, the Company entered into a Development, Commercialization and License agreement with Baxter International Inc. ("Baxter") for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas (the "License Agreement"). Baxter subsequently assigned the rights and obligations to the License Agreement to Baxalta Incorporated ("Baxalta"). Under the License Agreement, Baxalta has an exclusive, worldwide (subject to co-promotion rights) royalty-bearing, non-transferable license (which is sub-licensable under certain circumstances) relating to pacritinib. Licensed products under the License Agreement consist of products in which pacritinib is an ingredient.

49. According to the 2015 10-K, CTI received an upfront payment of $60 million under the License Agreement, which included a $30 million investment in CTI's equity. The License Agreement also provides for CTI to receive potential additional payments of up to $302 million upon the successful achievement of certain development and commercialization milestones, comprised of $112 million of potential clinical, regulatory, and commercial launch milestone payments, and potential additional sales milestone payments of up to $190 million.

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50. In June 2015, the Company and Baxalta amended the License Agreement (the "Amendment"). Pursuant to the Amendment, two potential milestone payments in the aggregate amount of $32 million from Baxalta to CTI were accelerated from the schedule contemplated by the License Agreement relating to the following: (i) the $20 million development milestone payment payable in connection with the first treatment dosing of the 300th patient enrolled per the protocol in PERSIST-2 (discussed below), referred to as the PERSIST-2 Milestone, and (ii) the $12 million development milestone payment payable in connection with the regulatory submission of the Marketing Authorization Application, or the MAA, to the European Medicines Agency, or EMA, with respect to pacritinib, referred to as the MAA Milestone.

51. The advances bore interest at an annual rate of 9% until the earlier of (i) the date of first occurrence of the respective milestone or (ii) the date that the respective advance plus accrued interest is repaid in full to Baxalta. Additionally, the 2015 10-K stated that "in the event that pacritinib development is terminated either because of a regulatory determination that the benefit/risk profile of the drug candidate is unacceptable or due to safety concerns or certain other reasons, including the failure of pacritinib to meet certain criteria or certain endpoints, … [referred to as the] Milestone Failure, … [the Company] would be required to repay the respective advance to Baxalta in eight quarterly installments beginning thirty days after the end of the calendar quarter of the first occurrence of a Milestone Failure and a final payment equal to the remainder of the unpaid balance, or the Repayment Terms." Additionally in the 2015 10-K, the Company stated that "in January 2016 and in February 2016, we successfully achieved the $20 million PERSIST-2 Enrollment Milestone and the $12 million MAA Milestone, respectively."

The FDA Approval Process

52. Before a drug can be sold in the United States, a drug company must obtain approval from the FDA. According to the FDA's website, most drugs that undergo preclinical

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(animal) testing never even advance to human testing and review by the FDA. The drugs that do advance to the next stage must undergo the agency's rigorous evaluation process, which scrutinizes everything about the drug – from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured.

See http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm

53. The first stage of the drug development and review process is the submission of an Investigational New Drug Application ("IND"). Sponsors, which include companies, research institutions, and other organizations that take responsibility for developing a drug, must disclose to the FDA results of preclinical testing in laboratory animals and what the proposed plan is for human testing. At this stage, the FDA decides whether it is reasonably safe for the company to proceed with testing the drug in humans. *Id.*

54. The FDA has 30 days to review the original IND submission. The process protects volunteers who participate in clinical trials from unreasonable and significant risk in clinical trials. The FDA responds to IND applications in one of two ways:

a. Approval to begin clinical trials; or

b. Clinical hold to delay or stop the investigation.

See http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.

55. The FDA can place a clinical hold for specific reasons, including:

a. Participants are exposed to unreasonable or significant risk;

b. Investigators are not qualified;

c. Materials for the volunteer participants are misleading; and

d. The IND application does not include enough information about the trial's risks. *Id.*

56. According to the FDA, a clinical hold is rare. Instead, the FDA often provides comments intended to improve the quality of a clinical trial. In most cases, if the FDA is

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satisfied that the trial meets Federal standards, the applicant is allowed to proceed with the proposed study. *Id.*

57. Clinical trials or, in other words, drug studies in humans, can begin only after an IND is reviewed by the FDA and a local institutional review board ("IRB"). The board is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research. *See* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm

58. IRBs approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details. IRBs make sure the study is acceptable, that participants have given consent and are fully informed of their risks, and that researchers take appropriate steps to protect patients from harm. *Id.*

59. To demonstrate the safety and efficacy of a drug, drug companies conduct the human clinical trials in three phases. Phase 1 studies are usually conducted in healthy volunteers in order to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. The number of subjects typically ranges from 20 to 80. *Id.*

60. If Phase 1 studies do not reveal unacceptable toxicity, then the drug companies move onto Phase 2. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on effectiveness. Phase 2 aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment – usually an inactive substance (placebo) or a different drug. During Phase 2, safety continues to be evaluated and short-term side effects are studied. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300. *Id.*

61. At the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale studies in Phase 3 should be done. The frequency with which the FDA meets

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with a sponsor varies, but the end of Phase 2 is one of two most common meeting points prior to submission of a New Drug Application ("NDA"). The other most common time is pre-NDA or, in other words, right before a new drug application is submitted. *Id.*

62. Phase 3 studies begin if evidence of effectiveness is shown in Phase 2. These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. *Id.*

63. The next step is submission of an NDA, which is the formal step a drug sponsor takes to request that the FDA consider approving a new drug for marketing in the United States. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured. When an NDA is submitted, the FDA has 60 days to decide whether to file it so that it can be reviewed. The FDA can refuse to file an application that is incomplete. For example, some required studies may be missing. *Id.*

64. The next step is the review of applications by the FDA. Although the FDA reviewers are involved with a drug's development throughout the IND stage, the official review time is the length of time it takes to review a new drug application and issue an action letter, which is an official statement informing a drug sponsor of the agency's decision. Once an NDA is filed, an FDA review team, which consists of medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts, evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use. Although no drug is absolutely safe, safe in this sense means that the benefits of the drug appear to outweigh the known risks. *Id.*

65. The review team analyzes study results and looks for possible issues with the application, such as weaknesses of the study design or analyses. Reviewers determine whether they agree with the sponsor's results and conclusions, or whether they need any additional

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information to make a decision. Additionally, sometimes the FDA calls on advisory committees, who provide the FDA with independent opinions and recommendations from outside experts on applications to market new drugs, and on FDA policies. Whether an advisory committee is involved depends on many things. *Id.*

66. Traditional approval requires that clinical benefit be shown before approval can be granted. Accelerated approval is given to some new drugs for serious and life-threatening illnesses that lack satisfactory treatments. This allows an NDA to be approved before measures of effectiveness that would usually be required for approval are available. *Id.*

The Development and Commercialization of Pacritinib

67. In the 2015 10-K, the Company states that its lead development candidate, pacritinib, is an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development, as well as inflammatory cytokine expression and immune responses. Mutations in these kinases have been shown to be directly related to the development of a variety of blood-related cancers, including myeloproliferative neoplasms, leukemia and lymphoma.

68. Additionally, the 2015 10-K stated that "in August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including, but not limited, to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant of, or whose symptoms are sub-optimally managed on, other JAK2 therapy. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need."

69. With respect to the Company's discussion concerning clinical trials involving pacritinib, the 2015 10-K stated the following, in relevant part:

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We are pursuing a comprehensive approach to advancing pacritinib for adult patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial; and the other in patients with low platelet counts, the PERSIST-2 trial. Myelofibrosis is a rare blood cancer associated with significantly reduced quality of life and shortened survival. As the disease progresses, the body slows production of important blood cells and within one year of diagnosis, the incidence of disease-related thrombocytopenia (very low blood platelet counts), severe anemia and red blood cell transfusion requirements increase significantly. Among other complications, most patients with myelofibrosis present with enlarged spleens (splenomegaly), as well as many other potentially devastating physical symptoms such as abdominal discomfort, bone pain, feeling full after eating little, severe itching, night sweats and extreme fatigue. We believe pacritinib may offer an advantage over other JAK inhibitors through effective treatment of symptoms while having less treatment-emergent thrombocytopenia and anemia than has been seen in the currently approved JAK inhibitor.

PERSIST-1 is a randomized (2:1), open-label, multi-center registration-directed Phase 3 registration-directed trial comparing the efficacy and safety of pacritinib with that of best available therapy other than JAK inhibitors, in 327 patients with myelofibrosis, without exclusion for low platelet counts. The primary endpoint for PERSIST-1 was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by MRI or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors. The secondary endpoint was the percentage of patients achieving a 50 percent or greater reduction in Total Symptom Score, or TSS, from baseline to week 24 as measured by tracking specific symptoms on a form, or Patient Reported Outcome, or PRO, instrument. At study entry, 46 percent of patients were thrombocytopenic; 32 percent of patients had platelet counts less than 100,000 per microliter (<100,000/μL); and 16 percent of patients had platelet counts less than 50,000 per microliter (<50,000/μL); normal platelet counts range from 150,000 to 450,000 per microliter. At the time of initiation of the trial, PERSIST-1 utilized the Myeloproliferative Neoplasm Symptom Assessment Form, or MPN-SAF TSS, the PRO instrument developed by Mayo Clinic, to measure TSS reduction. We collaborated with Mayo Clinic and the FDA and developed a modified instrument to be used as the endpoint for pacritinib clinical development. As a result, we amended the PERSIST-1 trial protocol to replace the original MPN-SAF TSS instrument with a new instrument, known as the MPN-SAF TSS 2.0, which is also being used for recording patient-reported outcomes for the PERSIST-2 trial. In connection with this amendment, we increased patient enrollment in the PERSIST-1 study from 270 to 327 patients. The trial enrolled patients at clinical sites in Europe, Australia, New Zealand, Russia and the U.S. The PRO Consortium, of which we are an active member, was formed by the non-profit Critical Path Institute in cooperation with the FDA and the medical products industry.

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> In May 2015, data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor) pacritinib therapy resulted in a significantly higher proportion of patients with spleen volume reduction and control of disease-related symptoms meeting the primary endpoint of the trial. Treatment with pacritinib resulted in improvements in severe thrombocytopenia and severe anemia, eliminating the need for blood transfusions in a quarter of patients who were transfusion dependent at the time of enrollment. Gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented at a late-breaking oral session at the 51st Annual Meeting of the American Society of Clinical Oncology Annual Meeting. Additionally, in June 2015, results from PERSIST-1 PRO and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation.

70. In the 2015 10-K, the Company went on to discuss its submission of an NDA and stated the following, in relevant part:

> In September 2015, following a pre-NDA meeting for pacritinib, we announced our plan to submit a rolling NDA to the FDA in the fourth quarter of 2015. In December 2015, we completed the NDA submission and requested marketing approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/μL) for whom there are no approved therapies. We were seeking accelerated approval and the NDA was based primarily on data from the PERSIST-1 Phase 3 trial, as well as data from Phase 1 and 2 studies and additional data requested by the FDA, including a separate study report and datasets for the specific patient population with low platelet counts of less than 50,000 per microliter (<50,000/μL) for whom there are no approved therapies.
>
> The PERSIST-2 trial is a randomized (2:1), open-label, multi-center registration-directed Phase 3 trial evaluating pacritinib compared to best available therapy, including the approved JAK inhibitor dosed according to product label, for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (≤100,000/μL). Patients are being randomized to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy. In October 2013, we reached an agreement with the FDA on a Special Protocol Assessment, or SPA, for the PERSIST-2 trial regarding the planned design, endpoints and statistical analysis approach of the trial. The SPA is a written agreement between us and the FDA regarding the design, endpoints and planned statistical analysis approach of the trial to be used in support of a

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> NDA submission. Under the SPA, the agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT scan from baseline to week 24 of treatment and the percentage of patients achieving a TSS reduction of 50 percent or greater using eight key symptoms as measured by the modified MPN-SAF TSS 2.0 diary from baseline to week 24. The design of PERSIST-1 and PERSIST-2 allows for patients on the BAT arm to crossover and receive treatment with pacritinib if their disease progresses or after they achieve the 24-week measurement endpoint. Although crossover design of clinical trials may confound evaluation of survival, such designs are frequently used in cancer studies, and the FDA has approved multiple oncology drugs that utilized crossover design in Phase 3 trials. The Independent Data Monitoring Committee, or IDMC, in place at the time for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival. After receiving input from external independent experts and providing the FDA the PERSIST-1 data, IDMC's recommendation and correspondence, we and Baxalta notified the FDA of the decision to proceed per protocol. Following a written response in lieu of a Type C meeting with the FDA, we and Baxalta determined that no modifications to the ongoing trials were required. Patient enrollment in PERSIST-2 was completed in February 2016 and over 300 patients were enrolled in North America, Australia, New Zealand and Russia. In early February, the FDA notified us that a full clinical hold has been placed on pacritinib. A full clinical hold is a suspension of the clinical work requested under an investigational NDA. Under the full clinical hold, all patients currently receiving pacritinib must discontinue pacritinib, and no new patients may start pacritinib as initial or crossover treatment.

Certain Defendants Cause CTI to Issue False and Misleading Statements

71. On March 3, 2014, the Company filed a Form 8-K along with an accompanying press release with the SEC entitled "CTI Opens Enrollment for PERSIST-2 Phase 3 Trial of Pacritinib for Patients with Myelofibrosis Who Have Low Platelet Counts", announcing the initiation of a Phase 3 clinical trial known as PERSIST-2 for the evaluation of pacritinib. The press release stated the following, in relevant part:

> **SEATTLE, Wash., March 3, 2014–**Cell Therapeutics, Inc. (CTI) (NASDAQ and MTA: CTIC) today announced the initiation of a Phase 3 clinical trial, known as PERSIST-2, which will evaluate pacritinib, a novel, investigational JAK2/FLT3 inhibitor, in patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (uL). The trial is expected to enroll

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> up to 300 patients in North America, Europe, Australia and New Zealand within 12 to 14 months. In October 2013, CTI reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the PERSIST-2 trial, which is a written agreement between CTI and the FDA regarding the planned design, endpoints and statistical analysis approach of the trial to be used in support of a potential New Drug Application, or NDA, submission. PERSIST-2 is the second of two planned Phase 3 trials in the pacritinib development program for myelofibrosis.
>
> *"JAK2 inhibitors have revolutionized the treatment of myelofibrosis by providing patients with an effective way to manage their disease," said Srdan Verstovsek, MD, PhD, principal investigator of PERSIST-2 and Professor, Leukemia Department, Division of Cancer Medicine, Chief, Section for Myeloproliferative Neoplasms, Leukemia Department, and Director, Clinical Research Center for MPNs, at The University of Texas MD Anderson Cancer Center. "However, I believe there remains a significant unmet medical need for new therapies, particularly for patients who present with or develop thrombocytopenia while on treatment. We are pleased to have the PERSIST-2 trial underway to evaluate the ability of pacritinib to address this issue."*

72. On March 4, 2014, the Company filed its annual report on Form 10-K with the SEC for the year ended December 31, 2013 (the "2013 10-K"). The 2013 10-K was signed by Defendants Nudelman, J. Bianco, L. Bianco, Bauer, Ignagni, Love, Mundinger, Singer, Telling and Tuckson.

73. Additionally, the 2013 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being

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prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

74. Additionally, the 2013 10-K stated the following with respect to the Company's clinical trials involving pacritinib, in relevant part:

> In January 2013, we initiated clinical trial sites and began enrolling patients with myelofibrosis in a Phase 3 clinical trial known as the PERSIST-1, or PAC325, trial. PERSIST-1 is a multicenter, open-label, randomized, controlled Phase 3 trial evaluating the efficacy and safety of pacritinib with that of best available therapy in patients with primary myelofibrosis. A total of approximately 320 eligible patients are expected to be randomized 2:1 to receive either pacritinib 400 mg taken orally once daily or the best available therapy. Best available therapy includes any physician-selected treatment other than JAK inhibitors, and there is no exclusion by patient platelet count.
>
> The primary endpoint of the PERSIST-1 trial is the percentage of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by MRI or computed tomography, or CT, scan. The secondary endpoint is the percentage of patients achieving a 50 percent or greater reduction in Total Symptom Score, or TSS, from baseline to 24 weeks as measured by tracking specific symptoms on a form. At the time of initiation of the trial, PERSIST-1 utilized the original Myeloproliferative Neoplasm Symptom Assessment (MPN-SAF TSS) instrument, to measure TSS reduction. However, we have substantially concluded the process of amending the PERSIST-1 trial protocol to replace the original MPN-SAF TSS instrument with a new instrument, known as the MPN-SAF TSS 2.0, which is also being used for recording patient-reported outcomes for the PERSIST-2 trial detailed below.

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> In connection with this amendment, we expect that enrollment in PERSIST-1 will be increased from 270 to approximately 320 patients. The trial is currently enrolling patients at clinical sites in Europe, Australia, New Zealand, Russia and the U.S. More details on the PERSIST-1 trial can be found at www.clinicaltrials.gov. We anticipate reporting topline data for PERSIST-1 in the second half of 2014.
>
> In March 2014, we opened clinical trial sites for enrollment of patients with myelofibrosis in the second Phase 3 clinical trial known as the PERSIST-2, or PAC326, trial. PERSIST-2 is a multi-center, open-label randomized, controlled clinical trial evaluating pacritinib in up to 300 patients with myelofibrosis whose platelet counts are less than or equal to 100,000/μL. The trial will evaluate pacritinib as compared to best available therapy, including approved JAK2 inhibitors that are dosed according to the product label for myelofibrosis patients with thrombocytopenia.

75. On April 29, 2014, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended March 31, 2014. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for

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external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

76. Additionally, the 10-Q stated the following with respect to the PERSIST clinical trials, in relevant part:

> Our lead development candidate, pacritinib, is an oral inhibitor of both Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase (FLT3), which demonstrated meaningful clinical benefit and good tolerability in myelofibrosis patients in Phase 2 clinical trials. Myelofibrosis is a blood-related cancer caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue, itching and pain. We believe pacritinib may offer an advantage over other JAK inhibitors through effective relief of symptoms with less treatment-emergent thrombocytopenia and anemia.
>
> In collaboration with Baxter International, Inc., or Baxter, pursuant to our worldwide license agreement to develop and commercialize pacritinib, or the Baxter Agreement, we are pursuing a broad approach to advancing pacritinib for patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013; and the other in patients with low platelet counts, the PERSIST-2 trial, which opened for enrollment in March 2014. In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment for PERSIST-2. The trial, together with PERSIST-1, is intended to support registration in the U.S. and the E.U. For additional information on this agreement, please see the discussion in Part I, Item 2, "License Agreements and Additional Milestone Activities – Baxter."

77. On August 4, 2014, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended June 30, 2014. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco

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certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

78. Regarding the PERSIST clinical trials, the 10-Q stated that "[w]e believe pacritinib may offer an advantage over other JAK inhibitors through effective relief of symptoms with less treatment-emergent thrombocytopenia and anemia," and "[i]n August 2014, we received a $20 million development milestone payment under the Baxter Agreement following completion of enrollment in PERSIST-1."

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79. On October 31, 2014, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended September 30, 2014. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

80. Additionally, with respect to the PERSIST clinical trials, the 10-Q stated the following, in relevant part:

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> In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment for PERSIST-2, which is actively enrolling patients. The two clinical trials are intended to support a New Drug Application, or NDA, planned regulatory submission in the U.S. in late 2015, followed by a planned Marketing Authorization Application submission in Europe in 2016. In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including but not limited to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant of, or whose symptoms are sub-optimally managed on, other JAK2 therapy. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

81. On March 12, 2015, the Company filed its annual report on Form 10-K with the SEC for the period ended December 31, 2014 (the "2014 10-K"). The 2014 10-K was signed by Defendants Nudelman, J. Bianco, L. Bianco, Bauer, Ignagni, Love, Mundinger, Singer, Telling and Tuckson.

82. Additionally, the 2014 10-K contained signed SOX certifications by Defendants J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of

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financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

83. With respect to the pacritinib clinical trials, the 2014 10-K stated the following, in relevant part:

> In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including, but not limited, to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant of, or whose symptoms are sub-optimally managed on, other JAK2 therapy. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The PERSIST-1 and PERSIST-2 clinical trials are intended to support a potential regulatory submission to the FDA or the European Medicines Agency, or the EMA.
>
> In March 2015, we reported top-line results for the primary endpoint from PERSIST-1 for the treatment of adult patients with myelofibrosis. The primary endpoint of the trial was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by magnetic resonance imaging, or MRI, or computerized tomography, or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry. For additional information concerning the top-line results, see Part I, Item 1, "Business—Development Candidates—Pacritinib—*Development in Myelofibrosis*".
>
> ***
>
> The safety profile in the trial was consistent with prior Phase 2 trials. While the most common treatment emergent adverse events were diarrhea, nausea and vomiting, the incidence of grade 3 events was lower than observed in Phase 2

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> trials. No grade 4 gastrointestinal adverse events were reported. Three patients discontinued therapy and nine patients required dose reduction for diarrhea. Preliminary analysis suggests that very few patients discontinued treatment while on pacritinib or required a dose reduction due to treatment-related anemia or thrombocytopenia. Additional data from ongoing analyses along with top-line results from PERSIST-1 will be submitted for presentation at a scientific meeting.
>
> Our ongoing PERSIST-2 trial is a multi-center, open-label, randomized, controlled Phase 3 trial evaluating pacritinib in up to 300 patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microlitre. This ongoing study is evaluating pacritinib as compared to best available therapy, including the approved JAK1/JAK2 inhibitor dosed according to the product label for myelofibrosis patients with thrombocytopenia. Patients are being randomized (1:1:1) to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy.
>
> In October 2013, we reached an agreement with the FDA on a SPA for the PERSIST-2 trial regarding the planned design, endpoints and statistical analysis approach of the trial to be used in support of a potential regulatory submission. Under the SPA, the agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT scan from baseline to week 24 of treatment and the percentage of patients achieving a TSS reduction of 50 percent or greater using eight key symptoms as measured by the modified MPN-SAF TSS 2.0 diary from baseline to week 24.

84. On May 6, 2015, the Company filed a current report on Form 8-K with the SEC along with an accompanying press release disclosing its financial results for the first quarter ended March 31, 2015 and stated the following with respect to the pacritinib clinical trials:

> *"After reporting positive top-line results from the PERSIST-1 Phase 3 clinical trial of pacritinib during the quarter, we have subsequently received positive feedback from a number of treating physicians who are excited by the potential opportunity for pacritinib to meet a current unmet medical need in the treatment of patients with myelofibrosis, specifically in the portion of patients that have low-blood platelets as a result of their disease or other treatment," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "We look forward to the oral presentation of data from this trial at ASCO and remain focused on completing the second pacritinib Phase 3 trial, PERSIST-2, in the second-half of this year and, with our partner Baxter, starting a planned regulatory submission late in 2015."*

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85. Also on May 6, 2015, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended March 31, 2015. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

86. On August 6, 2015, the Company filed a current report on Form 8-K along with an accompanying press release with the SEC announcing its financial results for the second quarter ended June 30, 2015 and providing the following update on pacritinib, in relevant part:

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"The significant interest from the oncology community generated by the Phase 3 PERSIST-1 clinical data, presented at the ASCO and EHA conferences, supports our belief that there remains a significant unmet medical need for patients with myelofibrosis and that pacritinib may play an important role in addressing the current treatment gaps for this disease," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "Armed with these positive data from the PERSIST-1 trial, our efforts are now directed toward exploring potential regulatory pathways in the U.S., while our partner Baxalta expects to submit a marketing application in Europe before the end of the year. Concurrently, we remain committed to completing the second pacritinib Phase 3 trial, PERSIST-2, and to continuing investigation into the potential for pacritinib in other blood-related cancers outside of myelofibrosis."

Second Quarter 2015 and Recent Highlights

Clinical:

- In May, data from the PERSIST-1 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis showed that, compared to best available therapy (exclusive of a JAK inhibitor), or BAT, pacritinib therapy resulted in a significantly higher proportion of patients with spleen volume reduction and control of disease-related symptoms. Treatment with pacritinib resulted in improvements in severe thrombocytopenia and severe anemia, eliminating the need for blood transfusions in a quarter of patients who were transfusion dependent at the time of enrollment. Gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented in a late-breaking oral session at the 51st Annual Meeting of the American Society of Clinical Oncology.

- In June, results from PERSIST-1 patient-reported outcome (PRO) and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association (EHA) showed significant improvements in symptom score with pacritinib therapy compared to BAT across the symptoms reported in the presentation.

- In June, data from an investigator-sponsored Phase 2 trial of tosedostat in elderly patients with either primary acute myeloid leukemia (AML), or AML that has evolved from myelodysplastic syndrome (MDS) showed that the combination of tosedostat with low-dose cytarabine/Ara-C (LDAC) resulted in an overall response rate of 54 percent in elderly patients with AML, with 45 percent of patients achieving durable complete responses. These findings were also presented at the EHA congress.

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87. Also on August 6, 2015, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended June 30, 2015. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

88. On September 24, 2015, the Company filed with the SEC its Registration Statement/Prospectus Supplement pursuant to Rule 424(b)(5) to complete the offering of 10,000,000 shares of common stock offered in connection with a Registration Statement

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initially filed with the SEC on November 21, 2014 on Form S-3. The Registration Statement/Prospectus Supplement was signed by Defendants Nudelman, J. Bianco, L. Bianco, Bauer, Ignagni, Love, Mundinger, Singer, Telling and Tuckson.

89. With respect to pacritinib, the Registration Statement/Prospectus Supplement stated the following, in relevant part:

> **Planned NDA Submission for Pacritinib**
>
> On September 23, 2015, we announced our plan to submit an NDA to the FDA following a productive pre-NDA meeting for pacritinib. We expect to submit the NDA in the fourth quarter of 2015 and to request accelerated approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/uL). The NDA will be based primarily on data from the PERSIST-1 Phase 3 trial —as well as data from Phase 1 and 2 studies of pacritinib—and additional information requested by the FDA, including a separate study report and datasets for the specific patient population with low platelet counts of less than 50,000 per microliter (<50,000/uL) for whom there are no approved drugs. Submission of an NDA after a single Phase 3 trial under accelerated approval, instead of waiting to complete two Phase 3 trials, could potentially reduce time to market by up to 14 months.

90. On November 5, 2015, the Company filed a current report on Form 8-K along with an accompanying press release announcing its financial results for the third quarter ended September 30, 2015. The press release stated the following with respect to pacritinib, in relevant part:

> *"We are focused on preparing our NDA submission for pacritinib and are on track to submit our application to the FDA this quarter," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "We also remain committed to completing the second Phase 3 trial of pacritinib, PERSIST-2, which we believe could serve as a post-approval confirmatory trial in the event our NDA application is accepted and approved under accelerated approval. Additionally, we look forward to upcoming data presentations of pacritinib and tosedostat studies at the ASH Annual Meeting in December."*

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Third Quarter 2015 and Recent Highlights

In September 2015, announced plans to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) with partner Baxalta Inc. for pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R for the treatment of patients with myelofibrosis, in the fourth quarter of 2015 and to request accelerated approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/uL) for whom there are no approved drugs. Priority review of the application will be requested at the time of NDA submission.

In September 2015, completed registered direct offering resulting in net proceeds of approximately $15.1 million and in October 2015, completed underwritten public offering resulting in net proceeds of approximately $46.5 million.

In November 2015, announced the upcoming presentations of data highlighting pacritinib and tosedostat at the 57th American Society of Hematology Annual Meeting (ASH) to be held December 5-8, 2015, in Orlando, FL.

91. Also on November 5, 2015, the Company filed its Quarterly Report on Form 10-Q with the SEC for the period ended September 30, 2015. The Form 10-Q was signed by Defendants J. Bianco and L. Bianco and also contained signed SOX certifications by J. Bianco and L. Bianco certifying that they are "responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant to have":

a. "Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared";

b. "Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our

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supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;" [and]

c. "Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation."

92. The above statements contained in ¶¶ 70, 72-79, 81-86, 88-89 were materially false and misleading when made because Defendants failed to disclose: (i) that pacritinib was attributed as a potential cause in the death and injuries of several patients; (ii) that the Company's clinical trials showed the dangers of pacritinib usage; (iii) that the Company's new drug application for pacritinib would likely be withdrawn; (iv) that, as such, the Company's future revenues were impaired; (v) that the Company lacked adequate internal controls; and (vi) that, as a result of the foregoing, the Company's and/or Defendants' statements about CTI's business, operations, and prospects were materially false and misleading at all relevant times.

The FDA Places Clinical Hold on Pacritinib

93. On February 8, 2016, CTI filed a current report on Form 8-K along with an accompanying press release with the SEC entitled "CTI Biopharma Provides Update on Investigational Agent Pacritinib." The press release announced that the FDA had placed a partial clinical hold on the pacritinib clinical studies and stated the following, in relevant part:

> ***FDA Places Partial Clinical Hold on Pacritinib IND; Currently Enrolled Patients Benefiting from Pacritinib Can Continue Receiving Pacritinib***
>
> ***Phase 3 Clinical Trial (PERSIST-2) Evaluating Pacritinib for Patients with Myelofibrosis and Platelet Counts of 100,000/µL has Completed Enrollment***
>
> **SEATTLE, February 8, 2016** – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA:CTIC) today announced that the Company received

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written communication from the U.S. Food and Drug Administration (FDA) on February 4, 2016, that the FDA has placed a partial clinical hold on the clinical studies being conducted under the Company's Investigational New Drug ("IND") application for pacritinib. This clinical hold impacts part of the clinical work currently being conducted under the IND and will also affect planned clinical trials.

Under the partial clinical hold, clinical investigators may not enroll new patients or start pacritinib as initial or crossover treatment, and patients not deriving benefit after 30 weeks of pacritinib treatment should stop using pacritinib. In addition, ***the FDA has recommended that the Company make certain modifications of protocols, including modifying all protocols for randomized trials to disallow crossover to pacritinib,*** provide certain notifications, revise relevant statements in the related investigator's brochure and informed consent documents, and take certain other actions. The Company intends to implement the FDA's recommendations. All clinical investigators worldwide have been delivered a notice of the partial clinical hold.

The Company intends to work together with the FDA and expects to submit modifications and revisions that address the recommendations noted above. In its written notification, ***the FDA cited the reasons for the partial clinical hold were that there was excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial. The excess mortality was most evident during the non-randomized crossover period following the initial 24 weeks of randomized treatment, during which patients in the control arm could switch to pacritinib treatment.*** In prior correspondence, the FDA acknowledged the difficulty addressing non-significant results, and that crossover designs can confound the interpretation of safety as well as the evaluation of survival.

After submission of the required information, the FDA has indicated that it would notify the Company whether it can continue the clinical studies under the IND.

Completion of PERSIST-2 Phase 3 Trial

Additionally, CTI BioPharma announced that as of February 3, 2016, it has completed patient enrollment in the PERSIST-2 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis. PERSIST-2 is evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (□100,000/µL). Under the FDA partial clinical hold referenced above, patients currently receiving pacritinib may continue to do so unless they are not deriving benefit after 30 weeks of pacritinib treatment, and crossover of patients from the control arm to the pacritinib arm will not be allowed.

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(Emphasis added).

94. On this news, shares of CTI declined $0.68 per share, or over 60%, from its previous closing price, to close at $0.44 per share on February 8, 2016.

95. On February 10, 2016, the Company filed a current report on Form 8-K along with an accompanying press release with the SEC entitled "CTI Biopharma Provides Update on Clinical hold of Investigational Agent Pacritinib and New Drug Application in U.S." The press release announced that the FDA had placed a full clinical hold on the Company's IND for pacritinib, and stated the following, in relevant part:

> **SEATTLE, February 9, 2016** – CTI BioPharma Corp. (CTI BioPharma) (NASDAQ and MTA:CTIC) today provided an update regarding the clinical studies being conducted under the Company's Investigational New Drug ("IND") application for pacritinib. Following the issuance of the Company's February 8, 2016, press release describing the partial clinical hold issued by the U.S. Food and Drug Administration (FDA) regarding those clinical studies, the Company received an oral communication from the FDA followed by a letter notifying the Company that the Company's IND for pacritinib has been placed on full clinical hold. The Company has withdrawn its New Drug Application (NDA) until the Company has had a chance to review the safety and efficacy data from the PERSIST-2 Phase 3 clinical trial and decide next steps.
>
> The FDA's February 8, 2016 letter notes the interim overall survival results from PERSIST-2 show a detrimental effect on survival consistent with the results from PERSIST-1. The deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. The FDA made recommendations that supersede the recommendations made by the FDA in connection with the partial clinical hold imposed by the FDA on February 4, 2016. The current recommendations include conducting dose exploration studies for pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols. In addition, the FDA recommended that the Company request a meeting prior to submitting a response to full clinical hold.
>
> Under the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately and no patients can be enrolled or start pacritinib as initial or crossover treatment.

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> All clinical investigators worldwide have been delivered a notice of the full clinical hold.

96. On this news, shares of CTI declined $0.20 per share, or 40%, from its previous closing price, to close at $0.30 per share on February 10, 2016, on unusually heavy volume of over 18 million shares.

The IDMC's Recommendation and the Board's Knowledge Thereof

97. The Board is responsible for overseeing the Company's oncology portfolio and its clinical trial design. As set forth in the Company's proxy statements filed with the SEC on July 29, 2015 and March 17, 2016 under the section entitled "Governance Highlights," the Company stated that it has a "standing Scientific Advisory Board comprised of industry veterans to, among other things, assist the Board in its oversight of the Company's oncology portfolio and clinical trial design."

98. As previously mentioned, on September 24, 2015, the Company filed with the SEC its Registration Statement/Prospectus Supplement pursuant to Rule 424(b)(5) to complete the offering of 10,000,000 shares of common stock. In the Registration Statement/Prospectus Supplement, the Company disclosed the following with respect to the design of the pacritinib clinical trials, in relevant part:

> ***The design of PERSIST-1 and PERSIST-2 allows for patients on the best availability therapy arm to crossover*** and receive treatment with pacritinib if their disease progresses or after they achieve the 24-week measurement endpoint. Although crossover design of clinical trials may confound evaluation of survival, such designs are frequently used in cancer studies, and the FDA has approved multiple oncology drugs that utilized crossover design in Phase 3 trials. ***The Independent Data Monitoring Committee, or IDMC, for the PERSIST program recommended patients on the best available therapy, or BAT, arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks***, which crossover confounds evaluation of survival. After receiving input from external independent experts and providing the FDA the PERSIST-1 data, IDMC's recommendation and correspondence, ***we and Baxalta notified the FDA of the decision to proceed per protocol.*** Following a written response in lieu of a Type C meeting with the FDA, we and Baxalta ***determined that no modifications to the ongoing trials were required.*** Enrollment in PERSIST-2, which is designed

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> to enroll up to 300 patients in North America, Europe, Australia, New Zealand and Russia is continuing.

(Emphasis added).

99. In other words, although the design of the pacritinib phase 3 trials (PERSIST-1 and PERSIST-2) allows for patients on the best available therapy arm to crossover and receive treatment with pacritinib after they achieve a certain measurement endpoint, the IDMC in place for the PERSIST trials recommended against allowing patients to crossover due to safety concerns. Yet, despite the IDMC's recommendation, CTI decided not to follow the IDMC's advice and advised the FDA that it had decided to proceed "per protocol."

100. According to the FDA, a clinical trial data monitoring committee or, DMC, is a "group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing trials. The DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial."

See http://www.fda.gov/RegulatoryInformation/Guidances/ucm127069.htm.

101. Additionally, the DMC also has other responsibilities including but not limited to, making recommendations to the sponsor of the clinical trial (which, in this instance, is CTI). Indeed, the FDA has issued the following guidance regarding a DMC's responsibility to make recommendations:

> A fundamental responsibility of a DMC is to make recommendations to the sponsor (and/or, as noted in the Introduction, a steering committee or other group delegated by the sponsor to make decisions about the trial) concerning the continuation of the study. ***Most frequently, a DMC's recommendation after an interim review is for the study to continue as designed.*** Other recommendations that might be made include study termination, ***study continuation with major or minor modifications,*** or temporary suspension of enrollment and/or study intervention until some uncertainty is resolved.
>
> Because a DMC's actions potentially impact the safety of trial participants, it is important that a DMC express its recommendations very clearly to the sponsor. Both a written recommendation and oral communication, with opportunity for

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> questions and discussion, can be valuable. Recommendations for modifications are best accompanied by the minimum amount of data required for the sponsor to make a reasoned decision about the recommendation, and the rationale for such recommendations should be as clear and precise as possible. Sponsors may wish to develop internal procedures to limit the interim data released by a DMC after a recommendation until a decision is made regarding acceptance or rejection of the recommendation, to facilitate maintaining confidentiality of the interim results should the trial continue. We recommend that a DMC document its recommendations, and the rationale for such recommendations, in a form that can be reviewed by the sponsor and then circulated, if and as appropriate, to IRBs, FDA, and/or other interested parties. Sections 5 and 7.2.1 address implications for reporting to FDA of DMC recommendations for major study changes such as early study termination.

Id. (Emphasis added).

102. Because one of the IDMC's primary responsibilities is to monitor safety while clinical trials are taking place, the Company should have followed the IDMC's recommendation advising against allowing patients to crossover. At the very least, the IDMC's concerns should have been a huge red flag to the Board that a committee of experts were concerned about the design of the PERSIST clinical trials resulting in potential adverse safety events and the Board should have taken steps to monitor the data from the clinical trials and/or review the IDMC's recommendation. Indeed, as demonstrated by the statements in the Company's 2015 Proxy and 2016 Proxy, the Board was responsible for the oversight of clinical trial designs and given that Individual Defendants Nudelman, J. Bianco, L. Bianco, Bauer, Ignagni, Love, Mundinger, Singer, Telling and Tuckson were all signatories to the Registration Statement/Prospectus Supplement which contained the foregoing information about the IDMC's recommendation, the Board is presumed to have had knowledge of the IDMC's recommendation and the Company's decision to proceed "per protocol" and not make any modifications to its ongoing clinical trials.

103. Yet, in breach of their fiduciary duties, the Board in bad faith consciously disregarded the IDMC's recommendation and as a result, on February 8, 2016, the Company announced that the FDA had placed a partial clinical hold on the clinical studies being

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conducted under the Company's IND application for pacritinib due to "excess mortality and other adverse events in pacritinib-treated patients compared to the control arm in the PERSIST-1 trial. The excess mortality was most evident during the non-randomized crossover to pacritinib . . ." In other words, the reasoning behind the FDA's decision to place a partial clinical hold on the Company's pacritinib trials was identical to the IDMC's recommendation to the Company to make changes to its clinical trials to prevent patients from crossing over, which the Individual Defendants chose to ignore.

104. As a result of the foregoing and as previously discussed, on February 10, 2016, the Company announced that the FDA placed a full clinical hold on pacritinib (i.e. a suspension of the clinical work requested under the IND) because of "interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest."

DAMAGES TO CTI CAUSED BY THE INDIVIDUAL DEFENDANTS

105. As a direct and proximate result of the Individual Defendants' misconduct, CTI failed to maintain proper internal controls, caused the Company to release false and misleading statements and substantially damaged the Company's credibility, corporate image and goodwill.

106. CTI has expended and will continue to expend significant sums of money. Additional expenditures and damages that the Company has incurred as a result of the Individual Defendants' breaches of their fiduciary duty include:

a. costs incurred from investigating, defending and paying any settlement or judgment in the Securities Class Actions for violations of federal securities laws;

b. costs incurred from conducting additional studies and/or for pacritinib in patients with myelofibrosis;

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c. costs incurred from complying with the FDA's recommendations to the Company in connection with the FDA's decision to place a full clinical hold on the Company's IND for pacritinib, including, but not limited to, conducting dose exploration studies for pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols;

d. costs incurred from preparing and resubmitting the NDA for pacritinib;

e. costs incurred from the loss of CTI's customers' confidence in the Company's services; and

f. costs incurred in connection with the SEC investigation and possible fines and/or penalties based on the SEC's findings.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

107. Plaintiffs bring this action derivatively in the right and for the benefit of CTI to redress injuries suffered, and to be suffered, by CTI as a direct result of breaches of fiduciary duty and unjust enrichment.

108. Plaintiffs are shareholders of CTI, were shareholders of CTI at the time of the wrongdoing alleged herein, and have been shareholders of CTI continuously since that time.

109. Plaintiffs will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights.

110. CTI is named as a nominal defendant in this case solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have. Prosecution of this action, independent of the current Board of Directors, is in the best interests of the Company.

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111. The wrongful acts complained of herein subject, and will continue to subject, CTI to continuing harm because the adverse consequences of the actions are still in effect and ongoing.

112. The wrongful acts complained of herein were unlawfully concealed from CTI shareholders.

113. Throughout the Relevant Period, the Individual Defendants made false and misleading statements about CTI's business, operations and prospects and violated multiple corporate governance principles, thus representing evidence of the Individual Defendants' breaches of fiduciary duties. The Individual Defendants breached the following corporate principles, among others:

a. Director nominees should have a background that demonstrates an understanding of the business, financial affairs and complexities of a multi-faceted, global pharmaceutical drug development business with commercialized operations, as well as general health care, science and technology matters;

b. Director nominees should possess fundamental qualities of intelligence, honesty, perceptiveness, good judgment, maturity, high ethics and standards, integrity, fairness and responsibility;

c. Director nominees shall have experience in "oversight of a company's compliance with key regulatory regimes, including, in particular, those pertaining to the U.S. Food and Drug Administration and the European Medicines Agency;"

d. Directors, officers and employees must comply with all applicable state and Federal health care laws, FDA and other regulations, rules and regulatory orders;

e. Directors, officers and employees must provide full, fair, accurate and

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timely disclosure in its public disclosures as well as in reports and documents filed with or submitted to, the SEC or NASDAQ; and

f. CTI also requires that its books and records be maintained in accordance with applicable accounting policies, laws, rules and regulations. These laws require, among other things, that CTI (1) maintain effective disclosure controls and procedures to ensure that all material information relating to CTI and its subsidiaries is made known to the persons responsible for preparing the company's financial reports and (2) have internal control over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

114. As a result of the facts set forth herein, Plaintiffs have not made any demand on the Current Director Defendants to institute this action since demand would be a futile and useless act because the Current Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action. The wrongful acts complained of herein show multiple breaches by the Individual Defendants, including the Current Director Defendants, of their fiduciary duties of loyalty, due care and oversight.

115. A majority of the Board is incapable of disinterestedly and independently considering a demand to commence and vigorously prosecute this action for the reasons set forth above and below.

116. As of the date of this Complaint, the Current Board consists of the following seven individuals: Defendants J. Bianco, Love, Nudelman, Singer, Telling, Tuckson and nonparty Matthew D. Perry.

117. Demand upon the Current Director Defendants is futile because a majority of the Board is already predisposed to refuse a demand as demonstrated by the Current Director

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Defendants' position on the merits of the allegations set forth in the Securities Class Actions, which allegations also form the basis, in part, of the liability of the Current Director Defendants in the instant litigation. In a Form 10-K filed by the Company on February 17, 2016, the Company stated the following, in relevant part:

> On February 10, 2016 and February 12, 2016, similar purported class action lawsuits entitled Ahrens v. CTI Biopharma Corp. et al, Case No. 1:16-cv-01044 and McGlothlin v. CTI Biopharma Corp. et al, Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Exchange Act Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib.
>
> The lawsuits seek damages in an unspecified amount. ***We believe that the allegations contained in the complaints are without merit*** and intend to vigorously defend ourselves against all claims asserted therein. A reasonable estimate of the amount of any possible loss or range of loss cannot be made at this time and, as such, we have not recorded an accrual for any possible loss.

(Emphasis added).

118. Thus, because the Current Director Defendants have already determined that they believe that the allegations in the Securities Class Actions are without merit, and because the instant action is substantially based on the same and/or similar misconduct as the Securities Class Actions, the Current Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this derivative action.

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119. Further, a majority of the Current Director Defendants are neither independent nor disinterested, thus rendering demand upon them as futile.

120. With respect to Defendant J. Bianco, J. Bianco is the principal founder of CTI and has served as the CEO and Director of the Company since September 1991. He also serves as the Company's President since July 2012, and previously served as President from February 1992 through July 2008. As conceded by the Company in the 2016 Proxy, Defendant J. Bianco, as an officer of CTI, is not an independent director due to his insider status. Additionally in the 2016 Proxy, the Company states that "Dr. Bianco's experience as a founder and executive of the Company and ***his knowledge of biopharmaceuticals*** were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." (Emphasis added). J. Bianco is the brother of Defendant L. Bianco, who is a named Defendant in the instant action and in the Securities Class Actions. Additionally, as demonstrated above, J. Bianco has repeatedly made and/or caused the Company to issue false and misleading statements to the public regarding the development of pacritinib. Additionally, J. Bianco was a member of the Company's Scientific Advisory Board, which was responsible for, among other things, assisting the Board in its oversight of the Company's oncology portfolio and clinical trial design. Further, J. Bianco signed or authorized the signing of the Registration Statement/Prospectus supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

121. With respect to Defendant Singer, Singer is one of the Company's founders and currently serves as the Executive Vice President, Chief Scientific Officer, Interim Chief Medical Officer and Global Head of Translational Medicine. Singer has also served as a Director of CTI since the Company's inception in September 1991. Additionally, Singer was the Company's Executive Vice President, Research Program Chairman and from April 1992 to

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July 1995, Singer served as the Company's Executive Vice President, Research and Development. As conceded by the Company in the 2016 Proxy, Defendant Singer, as an officer of CTI, is not an independent director due to his insider status. Also in the 2016 Proxy, the Company states "Dr. Singer's experience as a founder and executive of the Company and ***experience as a medical doctor and in the pharmaceutical and biotechnology industries*** were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." (Emphasis added). Additionally, Singer was a member of the Company's Scientific Advisory Board, which was responsible for, among other things, assisting the Board in its oversight of the Company's oncology portfolio and clinical trial design. Further, Singer signed or authorized the signing of the Registration Statement/Prospectus Supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

122. With respect to Defendant Love, Love is currently the Chair of the Audit Committee and is described by the Company as an "audit committee financial expert," as defined under the rules and regulations of the SEC and that he has accounting and related financial management expertise within the meaning of the NASDAQ Stock Market rules. He is also a member of the Compensation Committee and the Nominating and Governance Committee. According to the 2016 Proxy, the Company stated: "Mr. Love's ***many years of experience as an executive in the pharmaceutical biotechnology and medical research industries*** were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." (Emphasis added). Further, Love signed or authorized the signing of the Registration Statement/Prospectus Supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

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123. With respect to Defendant Nudelman, Nudelman is the Chair of the Nominating and Governance Committee and is a member of the Audit Committee and the Compensation Committee. According to the 2016 Proxy, the Company stated: "Dr. Nudelman's business and management experience and his experience investing in biotechnology companies were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." Further, Nudelman signed or authorized the signing of the Registration Statement/Prospectus Supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

124. With respect to Defendant Telling, Telling is the Chair of the Compensation Committee, and is also a member of the Audit Committee. According to the 2016 Proxy, the Company stated "Dr. Telling's business and ***industry experience*** as well as experience as a director of public companies were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." (Emphasis added). Further, Telling signed or authorized the signing of the Registration Statement/Prospectus Supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

125. With respect to Defendant Tuckson, Tuckson is a member of the Nominating and Governance Committee. According to the 2016 Proxy, the Company stated "Dr. Tuckson's ***experience as a healthcare executive*** and consultant across health and medical care sectors were the primary qualifications that have led the Board to conclude that he should serve as a director of the Company." (Emphasis added). Further, Tuckson signed or authorized the signing of the Registration Statement/Prospectus Supplement that contained false and misleading statements and is a named defendant in the Securities Class Actions and therefore

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faces a substantial likelihood of liability, rendering him incapable of independently exercising his business judgment and demand futile.

126. Additionally, as set forth above, the Current Director Defendants have substantial experience in the healthcare, pharmaceutical, biotechnology, biopharmaceutical and/or medical research industry. Further, the Board was responsible for overseeing the Company's oncology portfolio and its clinical trial design. Based on the foregoing, the Individual Defendants, including the Current Director Defendants, had a duty to monitor the clinical trials involving pacritinib, including ensuring that the design of the clinical trials did not result in adverse safety effects, and oversee the regulatory approval process with respect to pacritinib, especially given the fact that the Company's business is heavily dependent upon the successful development and commercialization of pacritinib. Indeed, this is demonstrated by the Company's recognition of the importance of obtaining FDA approval for pacrinitib and the significant harm the Company would likely face in the event that it was unable to commercialize pacritinib.

127. Specifically, the Company included the following risk factors in its 2015 10-K:

> *If our development and commercialization collaborations are not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize our compounds, which could have a material adverse effect on our business.*
>
> Our business is heavily dependent on the success of our development and commercialization collaborations. In particular, under the Servier Agreement and the Pacritinib License Agreement, we rely heavily on the respective entities, to collaborate with us to develop and commercialize PIXUVRI and pacritinib, respectively. As a result of our dependence on our relationships with Servier and Baxalta, the success or commercial viability of PIXUVRI and pacritinib is, to a certain extent, beyond our control. We are subject to a number of specific risks associated with our dependence on our collaborative relationship with Servier and Baxalta, including the following: possible disagreements as to the timing, nature and extent of development plans for the respective compound, including clinical trials or regulatory approval strategy; changes in their respective personnel who are key to the collaboration efforts; any changes in their respective business strategies adverse to our interests; possible disagreements regarding ownership of proprietary rights; the ability to meet our financial and

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other contractual obligations under the respective agreements; and the possibility that Servier or Baxalta could elect to terminate their respective agreements with us pursuant to "at-will" termination clauses or breach their respective agreements with us. Furthermore, the contingent financial returns under our collaborations with Servier and Baxalta depend in large part on the achievement of development and commercialization milestones and the ability to generate applicable product sales to trigger royalty payments. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large part on the performance of each of Servier and Baxalta. If our existing collaborations fail, or if we do not successfully enter into additional collaborations when needed, we may be unable to further develop and commercialize the applicable compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

***

If we are unable to address any recommendations or requirements of the FDA under the clinical hold for pacritinib to the satisfaction of the FDA on a timely basis or at all, we could be delayed or prevented from further studying pacritinib or seeking its commercialization.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib until we have had a chance to decide next steps. A full clinical hold is a suspension of the clinical work requested under an investigational new drug application. Under the full clinical hold, all patients currently on pacritinib were required to discontinue pacritinib, and we are not permitted to enroll any new patients or start pacritinib as initial or crossover treatment. In its written notification, the FDA noted interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. The recommendations include conducting Phase 1 dose exploration studies of pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols. In addition, the FDA recommended that we request a meeting prior to submitting a response to full clinical hold. All clinical investigators worldwide have been delivered a notice of the full clinical hold.

We plan to review the safety and efficacy data from the PERSIST-2 Phase 3 clinical trial and decide, next steps including addressing the FDA's recommendations. The FDA may not necessarily deem any information we provide or response we make sufficient to lift the full clinical hold on pacritinib or reduce it to a partial clinical hold. Additionally, the FDA may expand its

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information request or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size before the FDA will consider modifying of lifting the clinical hold, if at all. Complying with any such requests or making any such changes may be time-consuming expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to address the FDA's recommendations and requests in a manner satisfactory to the FDA, in a timely manner, or at all, we could be delayed or prevented from pursuing the further study of pacritinib and seeking its commercialization, which would prevent us from receiving future milestone or royalty payments, and otherwise significantly harm our business.

***

We or our collaboration partners may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our compounds.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the EMA in the E.U. Some of our other product candidates are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., we have not received marketing approval for our compounds. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. For instance, on February 8, 2016, the FDA placed pacritinib on full clinical hold and we subsequently withdrew our NDA for pacritinib until we have had a chance to decide next steps. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the compound is designed to address and the regulations applicable to any particular compound. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a compound for many reasons, including, but not limited to:

- A compound may not be shown to be safe or effective;
- The clinical and other benefits of a compound may not outweigh its safety risks;
- Clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- The results of clinical trials may not meet the level of statistical

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significance required by regulatory agencies for approval;

- Such regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- Such regulatory agencies may not approve the manufacturing process of a compound or determine that a third party contract manufacturers manufactures a compound in accordance with current good manufacturing practices, or cGMPs;
- A compound may fail to comply with regulatory requirements; or
- Such regulatory agencies might change their approval policies or adopt new regulations.

If our compounds are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

128. Thus, given the Board's recognition of the importance of obtaining regulatory approval for pacritinib, the Board should have been diligent in monitoring the clinical trials and ensuring that the trials were designed to prevent against adverse safety events. This is especially true for: (i) Defendant J. Bianco, whom the Company touted in the 2016 Proxy as having "knowledge of biopharmaceuticals;" (ii) Defendant Singer, whom the Company touted in the 2016 Proxy as having "experience as a medical doctor and in the pharmaceutical and biotechnology industries;" (iii) Defendant Love, whom the Company touted in the 2016 Proxy as having "many years of experience in the pharmaceutical biotechnology and medical research industries;" (iv) Defendant Telling, whom the Company touted in the 2016 Proxy as having business and industry experience; and (v) Defendant Tuckson, whom the Company touted in the 2016 Proxy as having "Experience as a healthcare executive and consultant across health and medical care sectors." Because of their failure to monitor the pacritinib clinical trials and to ensure that the design of the clinical trials would not result in adverse safety events, Defendants J. Bianco, Singer, Love, Telling and Tuckson face a substantial likelihood of liability rendering them incapable of independently exercising their business judgment and making demand futile.

129. Additionally, in the Company's quarterly report on Form 10-Q filed with the SEC on May 10, 2016, the Company disclosed, for the first time and almost five months later,

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that it had received a subpoena from the SEC in January 2016 requesting documents with respect to the pacritinib Phase 3 trials. The Form 10-Q stated the following, in relevant part:

> We are also in the process of providing documents in response to a subpoena received from the SEC in January 2016. The SEC's subpoena requests, among other things; internal and external communications related to pacritinib Phase 3 trials, ***including communications with the independent data monitoring committee, or IDMC, for pacritinib's Phase 3 trials, our steering committee, our board of directors, our audit committee***, representatives of Baxter and Baxalta, and the Food and Drug Administration, and other documents related to pacritinib. We believe that the SEC is seeking to determine whether there have been possible violations of the antifraud and certain other provisions of the federal securities laws related to the Company's disclosures concerning, among other things, the clinical test results of pacritinib. The SEC Staff's letter sent with the subpoena stated that the investigation is a fact-finding inquiry, and the investigation and subpoena do not mean that the SEC has concluded that we or anyone else has violated any law. We are cooperating with this investigation.

(Emphasis added).

130. The fact that the SEC subpoena is specifically targeted at Company communications, including but not limited to, communications involving the Board and the Audit Committee, demonstrates that the SEC believes that the Board and/or the Audit Committee may have had knowledge, authorized and/or approved the Company issuing false and misleading statements concerning the pacritinib Phase 3 trials and/or failing to disclose that the design of the trials could result in non-statistically significant safety concerns. Additionally, given that the entirety of the Board was responsible for overseeing the Company's oncology portfolio and its clinical trial design, it is highly likely that the Current Director Defendants had knowledge of the adverse safety events associated with pacritinib and the IDMC's recommendation to modify the Phase 3 trials to prohibit patients from crossing over. Yet, in breach of their fiduciary duties, the Board in bad faith consciously disregarded the IDMC's recommendation and decided to proceed "per protocol" which ultimately resulted in the FDA placing a full clinical hold on the Phase 3 trials. Accordingly, given that the Current Director Defendants face a substantial likelihood of liability for violating certain

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antifraud and federal securities laws based on the same and/or similar misconduct that is the subject of the instant complaint, the Current Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this derivative action.

131. Based on the foregoing, the Current Director Defendants, which constitute six out of seven members of the Board, face a sufficiently substantial likelihood of liability and accordingly, there is a reasonable doubt as to each Defendant's disinterestedness in deciding whether pursuing legal action would be in the Company's best interest. Accordingly, demand upon the Current Director Defendants is excused as being futile.

CAUSES OF ACTION

COUNT I

(Against The Individual Defendants for Breach of Fiduciary Duty)

132. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

133. The Individual Defendants owed and owe CTI fiduciary obligations, including the obligations of good faith, fair dealing, loyalty and care. The Individual Defendants breached their fiduciary duties by:

a. permitting the Company to issue materially false and misleading statements concerning the Company's business, financial performance and condition and the adequacy of its internal controls, resulting in the commencement of the Securities Class Actions; and

b. failing to ensure that the Company had an effective system of internal controls with respect to complying with all applicable laws, rules and regulations, including but not limited to, rules and regulations promulgated by the SEC, NASDAQ and/or the FDA; and

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c. recommending and/or approving a clinical trial design for pacritinib which resulted in adverse safety events; and

d. failing to conduct additional studies and/or review the data from the pacritinib clinical trial after the IDMC recommended that the Company modify the design of its clinical trial due to non-statistically significant safety concerns.

134. By reason of the foregoing, CTI was damaged.

COUNT II

(Against the Individual Defendants for Waste of Corporate Assets)

135. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

136. Defendants breached their fiduciary duties by failing to properly supervise and monitor CTI by allowing the Company to engage in an illegal, unethical and improper course of conduct.

137. As a result of the Individual Defendants' illicit course of conduct and breaches of fiduciary duty, the Company has incurred significant potential liability for legal and/or regulatory costs, penalties, fines, and/or fees in connection with the defense of the Individual Defendants' unlawful course of conduct complained of herein.

138. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

139. By reason of the foregoing, CTI was damaged.

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COUNT III

(Derivatively Against the Individual Defendants for Gross Mismanagement)

140. Plaintiffs incorporate by reference and reallege each of the foregoing allegations as though fully set forth herein.

141. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of CTI in a manner consistent with the operations of a publicly held corporation.

142. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, CTI has sustained significant damages.

143. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

A. Directing Defendants to account to CTI for all damages sustained or to be sustained by the Company by reason of the wrongs alleged herein;

B. Directing CTI to take all necessary actions to reform its corporate governance and internal procedures to comply with applicable laws and protect the Company and its shareholders from a recurrence of the events described herein, including, but not limited to, a shareholder vote resolution for amendments to CTI's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote on corporate governance policies;

C. Awarding Plaintiffs the costs and disbursements of this action, including reasonable attorneys' and experts' fees and expenses; and

D. Granting such other and further relief as the Court may deem just and proper.

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JURY DEMAND

Plaintiff demands a trial by jury for all issues so triable.

RESPECTFULLY SUBMITTED AND DATED this 24th day of May, 2016.

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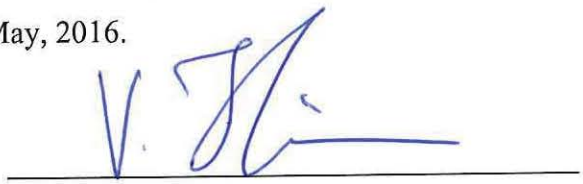
Attorneys for Plaintiffs

VERIFICATION

I, Thirukumaran Velayudhan, am one of the plaintiffs in this action. I am a shareholder of CTI Biopharma Corp. (the "Company"), and have been at all times throughout the Relevant Period. I have reviewed the allegations made in this Verified Shareholder Derivative Complaint and to those allegations of which I have personal knowledge I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true. Having received a copy of this Complaint, having reviewed it with my counsel, I hereby authorize its filing.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 19th day of May, 2016.



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VERIFICATION

I, Rajesh Nahar, am one of the plaintiffs in this action. I am a shareholder of CTI Biopharma Corp. (the "Company"), and have been at all times throughout the Relevant Period. I have reviewed the allegations made in this Verified Shareholder Derivative Complaint and to those allegations of which I have personal knowledge I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true. Having received a copy of this Complaint, having reviewed it with my counsel, I hereby authorize its filing.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 19th day of May, 2016.

RAJESH NAHAR